

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**75-105**

***APPLICATION NUMBER:***

**CORRESPONDENCE**



ALPHAPHARM

PHARMACEUTICALS

29th May, 1998.

Dr. James Wilson,  
OFFICE OF GENERIC DRUGS, CDER, FDA  
Document Control Room, Metro Park North II  
7500 Standish Place, Room 150  
ROCKVILLE, MD 20855-2773

NEW CORRESP

NC

Re: **FACSIMILE AMENDMENT for Indapamide Tablets USP 1.25 mg and 2.5 mg: A.N.D.A. # 75-105**

Dear Dr Wilson,

Further to your facsimile of May 19th 1998 detailing comments and deficiencies pertaining to the above ANDA, please find enclosed this Facsimile Amendment response.

The Chemistry Section (Part A) has been addressed in the enclosed Facsimile Amendment.

Should you have any further questions relating to this application please do not hesitate to contact us through our agent Mr. Bruce Goddard.

Yours sincerely,  
**ALPHAPHARM PTY. LTD.**

Brett Mooney, Ph.D.,  
**RESEARCH AND DEVELOPMENT MANAGER**

Encl.

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JUN 03 1998

GENERIC DRUGS

ALPHAPHARM

PTY. LIMITED

ACN 002 359 739

Head Office

12 Queen Street

GLIDE NSW 2037

PO Box 20

## BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-105

APPLICANT: Alphapharm Pty. Ltd.

DRUG PRODUCT: Indapamide 1.25 &amp; 2.5 mg tablet

The Division of Bioequivalence has completed its review and has no further questions at this time.

The dissolution testing will need to be incorporated into your stability and quality control programs as specified in U.S.P. 23.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale P. Conner, Pharm.D.  
Director Division of Bioequivalence  
Office of Generic Drugs  
Center for Drug Evaluation and Research



ALPHAPHARM

11th December, 1997.

Dr Jim Wilson  
OFFICE OF GENERIC DRUGS  
Document Control Room,  
Metro Park North II,  
7500 Standish Place, Room 150  
ROCKVILLE, MD 20855-2773

**RE: MAJOR AMENDMENT for Indapamide Tablets USP 1.25 mg and 2.5 mg: A.N.D.A. #75-105.**

Dear Dr Wilson,

Further to your correspondence of August 29th 1997 detailing comments and deficiencies pertaining to the above ANDA, enclosed is the Major Amendment for Indapamide Tablets USP 1.25 mg and 2.5 mg.

The comments and deficiencies in the Chemistry section and Labelling section have been addressed in the enclosed Major Amendment.

Please find enclosed two complete copies of this amendment- Archival copy (Blue Folder) and Chemistry section (Red folder). A signed Certification of the Field copy (Red Folder) as a true copy of the Major Amendment is also included.

In a separate Archival copy (Blue Folder) there is a secure copy of each of the following; final Printed Labels, final Patient Information leaflet, the side by side comparison of Alphapharms' revised patient information leaflet and the reference patient information leaflet with annotated differences. Also attached to this folder (in plastic sleeves) are 12 copies of the final Printed Labels and final Patient Information leaflets and 4 copies of the side by side comparison with annotated differences.

The updated stability data is included. Copies of the deficiency letter and the FDA Form 356h, signed by our U.S. agent, Lipha Pharmaceuticals Inc., are included.

ALPHAPHARM  
Pty Limited  
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CAMPERDOWN  
NSW 2050

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ACN 002 359 739

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GENERIC DRUGS

*Should you have any further questions regarding the information in this Major Amendment, please do not hesitate to contact our agent, Lipha Pharmaceuticals.*

*Yours sincerely*  
**ALPHAPHARM PTY. LTD.**

  
*Brett Mooney, Ph. D.,*  
**RESEARCH AND DEVELOPMENT MANAGER**

11th December, 1997

Dr Jim Wilson  
OFFICE OF GENERIC DRUGS  
Document Control Room,  
Metro Park North II,  
7500 Standish Place, Room 150  
ROCKVILLE, MD 20855-2773

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DEC 17 1997

**GENERIC DRUGS**

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2502 9666 4686

Manufacturing

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PO Box 16

ROCKFORD NSW

2500 000

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2502 9666 4686

2502 9666 4686

*Should you have any further questions regarding the information in this Major Amendment, please do not hesitate to contact our agent, Lipha Pharmaceuticals.*

*Yours sincerely*  
**ALPHAPHARM PTY. LTD.**

  
*Brett Mooney, Ph. D.,*  
**RESEARCH AND DEVELOPMENT MANAGER**

20/3/97

Dr. D.L. Sporn,  
Director of Generic Drugs,  
Centre for Drug Evaluation and Research,  
MPN-II, HFD-600,  
5600 Fishers Lane,  
**ROCKVILLE, MD 20857**  
U.S.A.

505 (j)(2)(a)(ok)  
One Marie H. Weikel  
5/9/97

**ORIGINAL ABBREVIATED NEW DRUG APPLICATION FOR INDAPAMIDE TABLETS  
USP 1.25 mg AND 2.5 mg.**

Dear Dr. Sporn,

Pursuant to Section 505 (j) of the Food, Drug and Cosmetics Act, Alphapharm Pty. Ltd. herewith submits an Abbreviated New Drug Application for Indapamide Tablets USP 1.25 mg and 2.5 mg. This Application is submitted on our behalf by our agent Lipha Pharmaceuticals Inc.. A letter appointing Lipha Pharmaceuticals Inc. as our Agent in the United States immediately follows this cover letter.

In support of this Application, the information outlined below is provided:

- 1) Patent Certification.
- 2) 356h Form, signed by our Agent, Lipha Pharmaceuticals Inc..
- 3) Index.
- 4) Chemistry, Manufacturing and Controls Information.
- 5) Draft labels/labelling. (The copies of the Draft labels/labelling are presented in a separate folder).
- 6) Methods Validation Package (one copy in the Archival (Blue folder), one copy in the Review (Red) Folder and one copy in the Field Submission Chemistry (Maroon) folder).

**ALPHAPHARM PTY LIMITED**

ACN 002 359 739

☐ **SYDNEY - Head Office:**

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PO Box 36, Camperdown NSW 2050

Telephone: (02) 9692 9777 Fax: (02) 9660 2344

☒ **BRISBANE - Manufacturing:**

Cnr Garnet & Antimony Sts, Carole Park QLD 4300

Telephone: (07) 3271 3244 Fax: (07) 3271 3087



7) *Bioavailability Study of Indapamide Tablets USP 1.25 mg and 2.5 mg.*


*A Two-Way Single-Dose Open-Label Fasting Bioavailability Study of Indapamide Tablets in Normal Healthy Non-Smoking Male Volunteers.*

*Enclosed please find three copies of this application. An Archival copy (Blue Folder), a Review copy divided into two parts: a Chemistry, Manufacturing and Controls data part (Red Folder), and a Bioavailability/bioequivalence data part (Orange Folder); and a Field Submission copy (Maroon Folder) of the Chemistry, Manufacturing and Controls Information for use prior to Preapproval Inspections.*

*We request that all information in this file be treated as confidential within the meaning of 21 CFR section 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your Office.*

*If you should have any questions regarding the information in this submission, please do not hesitate to contact our Agent, Lipha Pharmaceuticals Inc.*

*Yours Sincerely,*  
**ALPHAPHARM PTY. LTD.**

  
*Brett Mooney, Ph.D.*  
**RESEARCH AND DEVELOPMENT MANAGER**

20/3/97

Dr. D. L. Sporn,  
Director of Generic Drugs,  
Centre for Drug Evaluation and Research  
MPN-II, HFD-600  
5600 Fishers Lane,  
**ROCKVILLE, MD 20857**  
U.S.A.

**RE: ORIGINAL ABBREVIATED NEW DRUG APPLICATION FOR INDAPAMIDE  
TABLETS USP 1.25 mg AND 2.5 mg.**

Dear Dr. Sporn,

*This is to advise that Alphapharm Pty. Ltd. has nominated and appointed Lipha Pharmaceuticals Inc., 9 West 57th Street, Suite 3825, New York, NY 10019-2701, as its U.S. Agent and that Dr. Anita M. Goodman and other counsel in Lipha Pharmaceuticals Inc. are authorised to personally represent Alphapharm Pty. Ltd. in connection with this application and regulatory matters until further notice.*

Yours sincerely  
**ALPHAPHARM PTY. LTD.**



**Brett Mooney, Ph.D.,  
RESEARCH AND DEVELOPMENT MANAGER**

**ALPHAPHARM PTY LIMITED**  
ACN 002 359 739

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